510(k) SUMMARY OF SAFETY AND EFFECTIVENESS K021333

I. Submitter: George Wiseman, Ultralink LLC. 2083 Hawaii Ave., N.E. St. Petersburg, FL 33707 Ph: 727-527-1277 FAX 727-527-1945

II. Classification Names and Numbers: Ultrasonic Pulsed Echo Imaging System, 90-IYO, FR number 892.1560

III. Common/Usual Name: Ultrasound Bio Microscope

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IV. Proprietary Names: Artemis™ VHF Ultrasonic Arc-scan System

V. Establishment Registration Number: in progress

VI. Classification: Class II, Tier II. Described in CFR 892.1560

VII. Substantial Equivalence: The Artemis™ is substantially equivalent to the classified device described in CFR 21 892.1560, "Ultrasonic Pulsed Echo Imaging System," and to other ultrasound systems that have been cleared by the 510(k) process, particularly the Artemis™ VHF Ultrasonic Arc-scan System cleared by Ultralink LLC in K003890.

The 510(k) Substantial Equivalence Decision-making Process (detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to produce high-resolution ultrasound images of the anterior portion of the eye, and to measure these tissues such as the thickness of the cornea and its individual layers, the epithelium stroma and surgically induced surfaces. They can also be used to measure pathologic structures such as solid masses or cysts.
2. The technological characteristics of this device are the same as those for the predicate device except for the models of some of the components, and the method by which the arc-scanning motion is achieved.
3. The materials from which the patient-contact portions of the device are made are the same as in the predicate device.
4. The acoustic output of this device is similar to that of predicate devices and well below the preamendment levels described in the guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Mr. George D. Wiseman
President and CEO
ULTRALINK, LLC
2083 Hawaii Ave., N.E.
ST. PETERSBURG FL 33707

Re: K021333
Trade Name: Artemis VHF Ultrasonic Arc-Scan System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: August 14, 2002
Received: August 14, 2002

Dear Mr. Wiseman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Artemis VHF Ultrasonic Arc-Scan System, as described in your premarket notification:

Transducer Model Number

H40

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for David A. Legenon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510(k) Number: _____ Device Name: Artemis Ultrasonic Pulsed Echo Imaging System

Intended Use: To measure dimensions of components of the human eye.

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	✓	✓								
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: To provide tomographic, high-resolution ultrasound images of the anterior portion of the eye. It is also designed to measure these tissues and structures, such as anterior chamber depth, angle-to-angle width and sulcus-to-sulcus width. Measurement also may be made of pathologic structures such as solid masses or cysts and it therefore is useful in evaluation and/or planning of refractive surgery and evaluation of pathologies of the anterior segment such as trauma, tumors, cysts, glaucoma and hypotony.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

H4D transducer - Dd

Prescription Use (Per 21 CFR 801.109) ✓

David A. Seguine

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021333